

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : LaRosa Art Unit : 1644
Patent No.: 7,566,539 Examiner : Chun Dahle
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Title : ANTI-CCR2 ANTIBODIES AND METHODS OF USE THEREFOR

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being electronically filed in accordance with §1.6(a)(4) on the 8th day of March, 2010.

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Commissioner for Patents

REQUEST FOR RECONSIDERATION AND RECALCULATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d) AND IN VIEW OF WYETH

Pattees hereby request that the Patent Term Adjustment for U.S. Patent No. 7,566,539 (“the Patent”) be reconsidered. It is Patentee’s belief that the Patent Term Adjustment on the issued patent (set at 353 days as stated on the Patent cover sheet, which is attached as Exhibit A) is incorrect and that the Patent Term Adjustment to which the Patent is entitled is **786 days**.

This request is being submitted more than 180 days of the patent issue date. The patent issued July 28, 2009. However, this request is being submitted within two months¹ from the Federal Circuit decision in *Wyeth and Elan Pharma v. Kappos* (as U.S. Patent & Trademark Office Director) (Fed. Cir. 2010) (decided January 7, 2010) and the announcement from the United States Patent & Trademark Office that it would not appeal the Federal Circuit decision.

Under 37 CFR § 1.702, the grounds for reconsideration of Patent Term Adjustment include examination delays under the Patent Term Guarantee Act of 1999.

¹ The Federal Circuit decision in *Wyeth and Elan Pharma v. Kappos* was issued on January 7, 2010. Two months from January 7, 2010 was March 7, 2010 which was a Sunday.

The correct Patent Term Adjustment and the bases under § 1.702, and the relevant dates as specified in § 1.703(a) through (e) for which the adjustment is sought, and the adjustment as specified in § 1.703(f) to which the patent is entitled, follows.

37 CFR § 1.702(a). Under 37 CFR § 1.702(a) (hereinafter “Examination Delay”), Patentees are entitled to a period of patent term adjustment which is the sum of the following periods of delay:

A period of delay of 433 days due to failure by the U.S. Patent & Trademark Office (“the Office”) to mail an action under 35 USC § 132 not later than 14 months after the actual filing date (*i.e.*, by November 5, 2004) (hereinafter “14 Month Delay”) (see 37 CFR § 1.702(a)(1)). As the Office failed to mail an action under 35 USC § 132 until January 12, 2006, Patentees are entitled to a period of adjustment beginning on the day after the date that is 14 months after the date on which the above-referenced application was filed under 35 USC § 111(a), *i.e.*, November 6, 2004, and ending on the date of mailing of an action under 35 USC § 132, *i.e.*, January 12, 2006 (see 37 CFR § 1.703(a)(1)). Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 433 days, which is in agreement with the period calculated by the Office (see Patent Term Adjustment History downloaded from PAIR, submitted herewith as Exhibit B).

A period of delay of 68 days due to failure by the U.S. Patent & Trademark Office (“the Office”) to mail an action under 35 USC § 132 not later than 4 months after the date on which a reply was filed (*i.e.*, by January 15, 2009) (hereinafter “4 Month Delay”) (see 37 CFR § 1.702(a)(2)). Patentees are entitled to a period of adjustment beginning on the day after the date that is 4 months after the date on which a reply under § 1.111 was filed, *i.e.*, January 16, 2009, and ending on the date of mailing of a notice of allowance under 35 USC § 151, *i.e.*, March 24, 2009 (see 37 CFR § 1.703(a)(2)). Accordingly, the period of patent term adjustment due to the 4 Month Delay by the Office is 68 days, which is in agreement with the period calculated by the Office (see Patent Term Adjustment History downloaded from PAIR, submitted herewith as Exhibit B).

Patentees are entitled to a period of Examination Delay that is the period of the 14 Month Delay (433 days) and the period of the 4 Month Delay (68 days). Accordingly, Patentees are entitled to a total period of Examination Delay under 37 CFR § 1.702(a) of 501 days.

37 CFR § 1.702(b). In addition to the patent term adjustment due to Examination Delay according to 37 CFR § 1.702(a), Patentees respectfully submit that they are also entitled to a period of patent term adjustment under 37 CFR § 1.702(b) due to failure of the Office to issue a patent within three years after the date the corresponding application was filed under 35 USC § 111(a), *i.e.*, by September 5, 2006 (hereinafter “Three Year Delay”). The period of adjustment under 37 CFR § 1.702(b) is the number of days in the period beginning on the date after the date that is three years after the date on which the application was filed under 35 USC 111(a) (*i.e.*, September 6, 2006) and ending on the date a Request for Continued Examination was filed (*i.e.*, January 18, 2008) (see 37 CFR § 1.703(b)). Because the Office failed to issue the above-identified patent until July 8, 2009, which is more than three years after the filing date of the application under 35 USC § 111(a), Patentees are entitled to a period of patent term adjustment beginning on the day after the date that is three years after the filing date of the application (*i.e.*, September 6, 2006), and ending on the date that the Request for Continued Examination was filed (*i.e.*, January 18, 2008). Accordingly, the period of patent term adjustment due to the Three Year Delay by the Office is 500 days.

37 CFR § 1.703(f). As set forth in 37 CFR § 1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR § 1.702 (hereinafter “Office Delay”) reduced by the period of time equal to the period of time during which Patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR § 1.704 (hereinafter “Applicant Delay”).

With respect to the above-referenced application, the total period of Office Delay is the sum of the period of Examination Delay (501 days) and the period of Three Year Delay (500 days) *to the extent such periods of delay are not overlapping*.

As the period of the 14 Month Delay ended November 5, 2004 and the first day of the period of the Three Year Delay, *i.e.*, September 6, 2006, these periods do not overlap. As the last day of the period of the Three Year Delay ended January 18, 2008, and the first date of the 4 Month Delay occurred January 16, 2009, these periods do not overlap. Accordingly, Patentees submit that the total period of Office Delay is 1001 days, which is the sum of the period of the 14 Month Examination Delay (433 Days), the period of the 4 Month Delay (68 days) and the period of Three Year Delay (500 days).

37 CFR § 1.704. Under 37 CFR § 1.703(f), to calculate the period of patent term adjustment, the total period of Office Delay is reduced by the period of Applicant Delay as specified in 37 CFR § 1.704. The Office has calculated the period of Applicant delay to be 215 days. Patentees agree with this calculation.

Under 37 CFR § 1.704(b), at the time they were Applicants, Patentees agree to have delayed 61 days between the dates of November 6, 2006, and January 8, 2007, which is the period of time beginning on the date after the date that is three months after the date of mailing of an action by the Office (a Non-Final Action) and ending on the date of submission of Applicants' Response after Non-Final Action (see Exhibit B).

Under 37 CFR § 1.704(b), at the time they were Applicants, Patentees agree to have delayed 92 days between the dates of July 6, 2007, and October 5, 2007, which is the period of time beginning on the date after the date that is three months after the date of mailing of an action by the Office (Final Office Action) and ending on the date of submission of Applicants' Response after Final Action.

Under 37 CFR § 1.704(b), at the time they were Applicants, Patentees agree to have delayed 62 days between the dates of July 16, 2008, and September 15, 2008, which is the period of time beginning on the date after the date that is three months after the date of mailing of an action by the Office (Non-Final Office Action) and ending on the date of submission of Applicants' Response after Non-Final Action (see Exhibit B).

In view of the foregoing, Applicants delayed a total of 215 days (the sum of 61 days + 92 Days + 62 days), which is in agreement with the number of days calculated by the Office.

Calculation of Patent Term Adjustment. Under 37 CFR § 1.703(f), the period of patent term adjustment is the period of Office Delay reduced by the period of Applicant Delay. Accordingly, Patentees submit that the correct Patent Term Adjustment for the above referenced application is **786 days**, which is the difference between the total period of Office Delay (1001 days) and the period of Applicant Delay (215 days).

The above method of calculation of Patent Term Adjustment is consistent with the method supported by the Federal Circuit in *Wyeth and Elan Pharma v. Kappos* (as U.S. Patent & Trademark Office Director) (Fed. Cir. 2010) (decided January 7, 2010).

The above-identified patent is not subject to a terminal disclaimer.

Summary. In view of the foregoing, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **786 days**.

It is Patentees understanding that no fee is required for this request. However, if any fee is required and is otherwise absent, please charge any deficiency to Deposit Account No. 50/2762, referencing Attorney Docket No. M2051-701421.

Respectfully submitted,
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